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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,727	02/25/2004	Joseph L. Mark	65937-0045	2729

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EXAMINER

APANIUS, MICHAEL

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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05/15/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/786,727

Applicant(s)

MARK, JOSEPH L.

Examiner

Michael Apanius

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

Art Unit: 3736

DETAILED ACTION

1. This Office Action is in response to the amendment filed on 2/13/2007. The amendment is entered. The amendments to claims 1, 6, 9, 10, 14, 19, 22 and 23 and the amendments to the specification are acknowledged.

Claim Objections

2. Claims 1-13 objected to because of the following informalities: at claim 1, line 7, it appears that the first recitation of "in" should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-8 and 14-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Privatera et al. (US 6,273,862) in view of Moore (US 2,866,457).

5. Privatera discloses a biopsy system comprising a vacuum assisted biopsy device that communicates saline (column 18, 1st paragraph; column 21, lines 9-13) and/or an anesthetic (column 21, lines 14-16) to a piercer (70). However, Privatera does not

Art Unit: 3736

expressly disclose a fluid connector including two check valves configured to provide the two fluids in communication with the biopsy device.

6. Moore teaches a fluid connector for the purpose of simplifying and saving time in surgical procedures (column 1, lines 34-39). The fluid connector includes two check valves (9, 22) for providing fluid communication from one of two fluid sources (6, 26) to an output of the fluid connector.

7. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used the fluid connector taught by Moore in the system of Privatera in order to simplify and save time in surgical procedures by avoiding the need to change fluid connections and to manually open and shut valves.

8. In regards to claim 2, Privatera and Moore do not expressly disclose a duckbill valve member. However, Moore does state that any check valve well known in the art can be used. Applicant states that a duckbill-style valve is well known (paragraph 40). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a duckbill valve member as is well known in the art in place of the valve member of Moore because it is routine in the art to substitute alternative parts.

9. In regards to claims 3 and 4, the check valves of Moore comprise resiliently compressible valve members (around and including spring 25 in figure 1) secured in a valve seat (around 25 in figure 1).

10. In regards to claims 5-7, Privatera discloses the use of an isotonic solution (saline) and an anesthetic as noted above. Moore teaches the use of a bag (6) and a needleless syringe (26) for holding fluids.

Art Unit: 3736

11. In regards to claim 8, the check valves taught by Moore inherently have a predetermined cracking pressure.

12. The limitations of claims 14-21 are met as noted above.

13. Claims 11, 13, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Privatera et al. (US 6,273,862) as modified by Moore (US 2,866,457), as applied to claims 1-8 and 14-21 above, and further in view of Turturro et al. (US 6,331,165).

14. Privatera as modified by Moore does not expressly disclose luer fittings.

15. Turturro teaches luer fittings (column 18, lines 33-41) for the purpose of providing quick and easy connection and disconnection. Furthermore, male and female luer fittings are well known in the art and routinely used.

16. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used luer fittings as taught by Turturro and as are well known in the art to make the connections of Privatera as modified by Moore in order to provide a quick and easy means to connect and disconnect the fluid sources to the check valves.

17. Claims 1-10, 12, 14-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller et al. (US 2002/0082519) in view of Moore (US 2,866,457).

18. Miller discloses a biopsy system comprising a vacuum assisted biopsy device, a first fluid source (400 in figure 12), and a fluid connector (around 402) configured to

Art Unit: 3736

provide the first fluid source in communication with the biopsy device and including a check valve (402). Miller further discloses the use of a second fluid source (paragraph 90; "anesthetic"). However, Miller does not expressly disclose that the fluid connector includes a second check valve for providing the second fluid source in communication with the biopsy device.

19. Moore teaches a fluid connector for the purpose of simplifying and saving time in surgical procedures (column 1, lines 34-39). The fluid connector includes two check valves (9, 22) for providing fluid communication from one of two fluid sources (6, 26) to an output of the fluid connector.

20. In regards to claim 2, Miller and Moore do not expressly disclose a duckbill valve member. However, Moore does state that any check valve well known in the art can be used. Applicant states in the specification that a duckbill-style valve is well known (paragraph 40). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used a duckbill valve member as is well known in the art in place of the valve member of Moore because it is routine in the art to substitute alternative parts.

21. In regards to claims 3 and 4, the check valves of Moore comprise resiliently compressible valve members (around and including spring 25 in figure 1) secured in a valve seat (around 25 in figure 1).

22. In regards to claims 5-7, Miller discloses the use of an isotonic solution (saline; paragraphs 141-144) and an anesthetic. Moore teaches the use of a bag (6) and a needleless syringe (26) for holding fluids.

Art Unit: 3736

23. In regards to claim 8, check valves inherently have a predetermined cracking pressure.

24. In regards to claim 9, Miller discloses that the cracking pressure is less than or equal to a vacuum created in the fluid connector by the biopsy device (paragraph 143).

25. In regards to claim 10, Moore teaches that it is desirable to keep the two fluid sources isolated and that fluid can not pass the check valves in a wrong direction (column 2, lines 15-18). Therefore, the cracking pressure is greater than a vacuum created in the fluid connector when the second check valve is open in order to prevent backflow of one fluid into the other fluid source.

26. In regards to claim 12, Miller discloses drawing a predetermined amount of fluid from a fluid source (paragraph 142).

27. The limitations of claims 14-23 and 25 are met as noted above.

28. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used the fluid connector taught by Moore in the system of Miller in order to simplify and save time in surgical procedures by avoiding the need to change fluid connections and to manually open and shut valves.

Response to Arguments

29. Applicant's arguments regarding the outstanding prior art rejections have been fully considered but they are not persuasive.

30. Applicant argues that the check valve (9) of Moore is not integrated within the Y-connection (11), as set forth in claims 1 and 14. In response, it is respectfully noted that

Art Unit: 3736

the fluid connector taught by Moore is sufficient to meet the claim language. In particular, claim 1 requires a fluid connector including a first check valve integrated within the fluid connector and a second check valve integrated within the fluid connector. The claim language does not preclude the interpretation wherein the fluid connector of Moore includes elements (9, 11, 12, 13 and 22). Under this interpretation, the check valves are clearly integrated within the fluid connector. Claim 14 requires a body member having a first input port and a second input port wherein the first input port includes a first check valve integrated therein and wherein the second input port includes a second check valve integrated therein. Moore teaches a body member (11) having two input ports (33), wherein each check valve is integrated in the respective input port. Therefore, the teachings of Moore are considered sufficient to meet the amended claim language.

31. Applicant further argues that Moore does not state that the valve member itself may be resiliently compressible as claimed in claims 3 and 16. In response, it is noted that a spring is resiliently compressible and therefore the disclosure of Moore is sufficient to meet the language of claims 3 and 16.

32. In regards to Miller, Applicant argues that no fluid connector is shown around 402. The Examiner respectfully submits that Miller clearly shows a tube connecting the fluid source (400) to the check valve (404) in figure 12. This tube can be considered a fluid connector. However, this tube lacks a second check valve.

33. Applicant further argues that Miller clearly already provides two separate fluid sources that are in communication with the biopsy device and there would be no

Art Unit: 3736

motivation to look to Moore to provide a fluid connector for two separate sources. In response, Miller discloses the use of saline and anesthetic through the cannula hub. The fluid connector of Moore is beneficial because it can simplify and save time during surgical procedures that require multiple fluid sources. Thus, there is motivation to combine Miller with Moore to meet the claimed invention.

Conclusion

34. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

35. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.


37. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

Art Unit: 3736

number for the organization where this application or proceeding is assigned is 571-273-8300.

38. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA


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